K092471

510(K) Summary
Portable Gamma Camera: Sentinella 102

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510(k) number:

Owner's name: General Equipment for Medical Imaging, S. A.
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Date: 20th of May 2009

OCT - 2 2009

Name of the device: Sentinella 102
System trade name: Sentinella
Common name: Portable Gamma Camera
Classification name: Scintillation Gamma Camera, Class I. 21 CFR § 892.1100 (1990)

PREDICATED DEVICES

Product: LumaGEM™ Scintillation Camera
Manufacturer: Gamma Medica Instruments
510(k) number: K993813
Substantial Equivalence Date: 18/01/2000

Product: Anzai eZ-Scope AN Portable Gamma Camera
Manufacturer: Anzai Medical Company, Ltd.
510(k) number: K022342
Substantial Equivalence Date: 09/10/2002

DESCRIPTION

Sentinella 102 is a portable gamma camera system including a small gamma camera designed to obtain images from small organs and structures labeled using radionuclides emitting gamma-rays.

The Sentinella system also includes analysis and display equipment, a cart and ergonomic arm, which facilitates the equipment portability and positioning, and accessories.

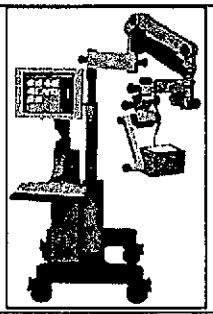
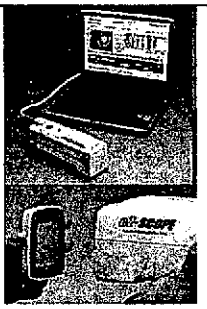
INDICATIONS FOR USE

Sentinella 102 is a mobile gamma camera system which is intended for imaging the distribution of radionuclides in the human body by means of photon detection. The images are intended to be interpreted by qualified personnel.
Sentinella 102 may be used intraoperatively if a protective sheath is used.
Sentinella 102 may be used at the patient's bedside, or in Emergency Room or Intensive Care Unit.

SUBSTANTIAL EQUIVALENCE CLAIM

Sentinella 102 has the same intended use as the legally marketed predicated devices **LumaGEM™ Scintillation Camera** (Gamma Medica Instruments), K993813, and **Anzai eZ-Scope AN Portable Gamma Camera** (Anzai Medical Company, Ltd.), K022342, and uses the same technology in position sensitive photomultiplier as the former. Instead of pixelated crystals as in all the previously mentioned devices, Sentinella employs continuous scintillation crystals, which give to Sentinella the possibility of mounting not only parallel-hole collimators but also diverging and pinhole.

Sentinella 102 is as safe and effective as the above-mentioned predicated devices. It meets safety requirements, EN 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety, UL 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety, EN 60601-1-2:2001 + A1:2006, Medical electrical equipment. Part 1-2: General requirements for safety. Collateral standard: electromagnetic compatibility bears the CE mark in accordance with the Medical Device Directive 91/42/EEC and meets the requirements of the NEMA NU 1: 2007: Performance Measurements of Gamma Cameras and for the laser mounted on the equipment it complies with the requirements of the IEC 60825-1: 2001: Safety of Laser Products – Part 1: Equipment classification, requirements and user's guide and the 21 CFR 1040: Performance Standards for light-emitting products.

	Sentinella 102	**LumaGEM™ Scintillation Camera**	**Anzai eZ-Scope AN Portable Gamma Camera**	**Justification of Substantially Equivalence in case of difference with predicates**
				
Indications for Use	Sentinella 102 is a mobile gamma camera system which is intended for imaging the distribution of radionuclides in the human body by means of photon detection. The images are intended to be interpreted by qualified personnel. Sentinella 102 may be used intraoperatively if a protective sheath is used. Sentinella 102 may be used at the patient's bedside, or in Emergency Room or Intensive Care Unit.	The LumaGEM™ scintillation camera is a camera system, which is intended for measuring and imaging the distribution of radionuclides in the human body by means of photon detection. These images are intended to be interpreted by qualified medical personnel.	The Anzai eZ-Scope AN Portable Gamma Camera is intended to produce both planar and tomographic images of a radio-marked source. It is indicated for use to image the distribution of radionuclides in the human body using planar imaging techniques. The eZ-Scope may be used intraoperatively or on pathological specimens if a protective sheath is used.	-
Target population	Same as predicates	Any population group	Any population group	-

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	Sentinella 102	LumaGEM™ Scintillation Camera	Anzai eZ-Scope AN Portable Gamma Camera	Justification of Substantially Equivalence in case of difference with predicates
Anatomical sites	Same as predicates	Any anatomical site	Any anatomical site	-
Where used	Same as predicates	Hospitals	Intraoperative and general ambulatory conditions	-
Personnel	Same as predicates	Physicians	Physicians	-
Energy used and/or delivered	Same as predicates	<20W	<20W	-
Human factors	Mobile ergonomic arm and cart, highly adaptable for manipulation close to the interest area. User autonomous screens with touch-screen options. Plug and play installation.	Mobile ergonomic workstand easily adjusts for standing or sitting operator. The imaging head is located on the arm that allows its positioning on the interest area. Monitor for imaging of the interest area.	Light, handheld and ideal for manipulation in close proximity to the body. Operation is straightforward and intuitive. Connected to a PC to imaging the interest area.	The Sentinella 102 is substantially equivalent with the predicates as it allows the positioning on the interest area. The presence of the two screens allows to the surgeon and the physician to see the same image simultaneously, one improvement refers to the predicates.
Design	The Sentinella 102 is composed of the following parts: - ergonomic cart on wheel base - articulated arm with laser positioning system (λ: 635nm typ., 640nm max,Power: 4mW, Class IIIR according to IEC 60825) - Handheld gamma camera included in a protective carrying case for transport. - Collimators: 2 pinhole and one divergent - 2 Screens 19", one of these with touch screen functions and PC. - Mouse and keyboard - Sentinella Software - Quality control kit	The LumaGEM is composed of the following parts: - cart on wheel base - articulated arm - detector head - Collimators: parallel - 1 PC with screen of 19" - Mouse and keyboard - LumaGEM Software	The Anzai eZ-scope is composed of the following parts: - Handheld gamma camera - Parallel collimators - Connected to a portable computer - eZ-SCOPE AN software - protective carrying case for transport	The Sentinella 102 includes a laser positioning system that helps the user to locate on the patient a determined point of the picture obtained in the interface, it is an improvement compared to the predicates. The laser incorporated in the Sentinella 102 has a wavelength of 635nm and an output power of 4mW, as a consequence it is classified as IIIa according to the 21 CFR 1041. The only potential risk of such laser is when it is exposed directly on the eye, but during its use, such laser has not to focus the eyes of the patient or the user, for another part the Sentinella 102 laser pointer system is labeled with the indication "DANGER – LASER RADIATION –AVOID DIRECT EYE EXPOSURE". It is only used for relative positioning on the body and works only when the user activates it. So it does not add any appreciable safely concerns compared to the predicates.

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	Sentinella 102	LumaGEM™ Scintillation Camera	Anzai eZ-Scope AN Portable Gamma Camera	Justification of Substantially Equivalence in case of difference with predicates
				The pinhole and the divergent collimators have equivalent characteristics and functionality, as detailed along this table, compared to the predicates. The quality control kit is an optional tool included in the equipment to check the calibration of the equipment. It is an improvement in reference to the predicates.
Materials	Same as predicates	Standard Electronic and Medical grade materials	Standard Electronic and Medical grade materials	-
Computer specifications	- PC with Intel Core Duo microprocessor - 1024 MBytes RAM. - 80 Gbytes of Hard Disk available. - Windows XP Operating System.	- PC with an Intel (Pentium II or higher) microprocessor. - It includes a minimum of 32 MB of RAM - a minimum of 4GB local disk space and recording CD-ROM as a secondary mass storage. - Windows NT operating system.	Laptop standard PC	-
Display LCD specification	Screen size: 19" Resolution: 1280 x 1024	Screen size: 15 inches or greater Resolution: 800 x 600	-	-
Patient database management	Sentinella patient database stores patient information (name, sex, age, address, phone, ID,) and intervention information (date, protocol, comments, acquired images). Each patient can have several interventions. The database relies on standard SQL technology, currently based on well-known, reliable and widely used PostgreSQL relational database. The database resides in local hard disk and periodic automatic backups are performed. Database could be located in a server and accessed though LAN, but Sentinella equipments are not delivered configured for LAN usage. The patient database is based on the Microsoft ADO.net engine. Database is managed from Sentinella Suite interface through the different modules (Sentinella Manager allows to manage	The patient database management involves both intermediate and historical archiving. The immediate archive database resides on a local or LAN based disk drive and the historical archive resides on a secondary mass storage device. The patient visit entry (patient name, ID, visit date) and each of the data set entries (dataset name, ID and creation date) are available from the main database interface. The patient database is based on the Microsoft DAO jet engine. It is a relational database organized in 4 levels: -Patient level: patient name and ID. -Visit level: for each patient, date of the visit, information about the visit -Study level: allows acquisition of protocol data grouping. -Dataset level: set of images (static, dynamic,	-	Although the structure of the database of the Sentinella equipment is different, the principle of functioning is similar: - As LumaGEM database, Sentinella database allows to register patients, visits (in this case interventions) and show images obtained at different time. - It could be accessed on local or LAN. - It is based on Microsoft ADO.net, database communication procedure equivalent to Microsoft DAO.

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	Sentinella 102	LumaGEM™ Scintillation Camera	Anzai eZ-Scope AN Portable Gamma Camera	Justification of Substantially Equivalence in case of difference with predicates
	patients and interventions, Sentinella OR does new interventions and acquires images, Sentinella Viewer allows to visualize the images for the different patients and interventions.	list mode, result of screen) The operations performed on the database are record operations: visit record, study record, visit record, dataset record. The interface is user friendly: for the operator, patient and visit levels are merged in one single level. The operator manipulates patient-visit entities. The operator does not have to know about the dataset level. His interaction stops at the study level.		
Arm vertical movement	65 cm	50.8 cm	-	The major range of the arm movement of the Sentinella 102 allow the precise location of the gamma camera on the interest area.
Electrical safety and EMC	Electrical safety standard compliance (EN 60601-1, UL 60601-1) EMC compliance (EN 60601-1-2)	EM emission of the Uninterruptible Power Supply (UPS) complies with 47 CFR Part 15 Subpart B: 1999. EM emission of the ViewSonic monitor satisfies the standard EEC directive 89/336/EEC, 92/31/EEC, 93/68/EEC	Meets electrical, electromagnetic interference and safety international standards. Fully compatible with other electronic devices for electrical and electromagnetic standards.	The gamma camera complies with the standard recognised by the FDA.
Compatibility with the environment	Same as predicates: Compliance of DIRECTIVE 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment	-	Enviroment-friendly during regular use and storage. To be disposed of properly.	-
Sterility	The product is not sterile and has not to be sterilized by the user. Cleaning standard procedure of medical devices. Can be used under sterile-intraoperative conditions if device is covered with a sterile cover as shown in user manual	The product is not sterile and has not to be sterilized by the user. Cleaning standard procedure of medical devices.	The product is not sterile and has not to be sterilized by the user. Can be used under sterile-intraoperative conditions if probe head is covered with a sterile protective sheath.	-
Planar imaging	Yes	Yes	Yes	-
Tomography	No	No	Yes	-
Energy range	50-200 keVs	30-300 keVs	71-364 keVs	The energy range covered contains the major part of the radionuclides commonly used in surgery (Tc, Co, Ba, Am, Gd)
Energy resolution	15.9 %	5 %	7 %	Although the energy resolution is larger, the energy window is about 10% according to the NEMA. As a consequence the Sentinella 102 detects the same events than

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				the predicates.
Crystal Technology	Continuous CsI (Na)	Pixelized cadmiun-zinc-telluride (CZT)	Pixelized cadmiun-zinc-telluride (CZT)	The crystal used with the Sentinella 102 has less electronic noise, better performance in terms of spatial resolution and sensibility in reference to the predicates.
Intrinsic spatial resolution	1,8 mm	2 mm	2 mm	The difference of intrinsic spatial resolution is not appreciable.
Spatial resolution	Green collimator (Ø 2.5 mm) 5,4mm @ 3cm 7.3 mm @ 5cm Blue Collimator (Ø 4 mm) 8,2mm @ 3cm 11,1mm @ 5cm Grey collimator, divergent 6,3mm@ 3cm 8,2mm @ 5cm	LEHR collimator < 4,25 mm @ 2,5cm < 5,5mm @ 5cm LEAP collimator < 6,0mm @ 2,5cm < 7,5mm @ 5cm	-	The spatial resolution changes with the collimator used. The spatial resolution of the Sentinella 102 collimators are in the same range of values compared to the predicates, so they could be considered as equivalent.
Sensitivity (cpm/µCi)	Green collimator (Ø 2.5 mm) ~300 @ 3cm 110 @ 5cm 38 @ 10cm Blue Collimator (Ø 4 mm) ~z<600 @ 3cm 233 @ 5cm 87 @ 10cm Grey collimator, divergent 104 @ 5cm 72 @ 10cm	LEHR >130 LEAP >250 LEHS >500		The sensitivity depends on the distance of the gamma camera to the radioisotope detected with pinhole and divergent collimators. The sensitivity of the Sentinella 102 collimators are in the same range of values compared to the predicates, so they could be considered as equivalent.
Flood field Uniformity	5 %	< 4%	-	The data obtained with the Sentinella 102 are equivalent with the predicates.
Field Of View	15 x 15 cm at 20 cm from collimator	13 x 13 cm (5"x 5")	3.2 x 3.2 cm	Equivalent with the predicates
Height	160 – 215 cm	139.7 cm	-	The Sentinella 102 is higher that the predicates but its height allows its transport in any hospital or medical centre.
Communication	DICOM	DICOM, Interfile	Not specified	-
Power	AC100-240V, 50/60 Hz	AC100-240V, 50/60 Hz	AC100-240V, 50/60 Hz	-
Compatible accessories	Gamma Probe S-Probe Sterile covers Radioactive Pointer (^{153}Gd, activity of 60 µCi)	-	Sterile protective sheath	Radioactive pointer: According to the standard RS-G-1.7: "Application of the concepts of exclusion, exemption and clearance" of the IAEA, the gadolinium pointer of 60µCi is exempted because its activity is inferior to 10Bq/g (270 µCi). As a consequence its use and manipulation does not present any risks for the patients

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				and the sanitary personnel. For another part the dose received by the patient during the use of the pointer (60µCi during less than 30 minutes) is negligible compared with the dose injected to the patient to perform any gammagraphy (for instance with the Lumagem or Anzai gamma camera) which around 20 mCi. The dose of the pointer represents less than 0,3% of the dose injected, so we could consider that the radioactive pointer does not add safety concerns compared to the predicates. The compatible accessories of the Sentinella 102, the Gamma Probe S-Probe and the radioactive pointer not presented in the predicates help the user to locate on the patient a determined point of the picture obtained in the interface, they are an improvement compared to the predicates.

All the mentioned differences do not compromise the intended use and safety, but in fact, demonstrate that the Sentinella 102 is as effective as the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

General Equipment for Medical Imaging, S.A.
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd
MELVILLE NY 11747

OCT - 2 2009

Re: K092471
Trade/Device Name: Sentinella 102
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: September 18, 2009
Received: September 22, 2009

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K092471

Device Name: **Sentinella 102**

Indications for Use:

Sentinella 102 is a mobile gamma camera system which is intended for imaging the distribution of radionuclides in the human body by means of photon detection. The images are intended to be interpreted by qualified personnel.
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092471